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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/795,843

03/08/2004

Dilip K. Nakhasi

0803-0111

1274

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7590

09/28/2010

COOK ALEX LTD

SUITE 2850

200 WEST ADAMS STREET

CHICAGO, IL 60606

EXAMINER

PADEN, CAROLYN A

ART UNIT

PAPER NUMBER

1781

MAIL DATE

DELIVERY MODE

09/28/2010

PAPER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/795,843
Filing Date: March 08, 2004
Appellant(s): NAKHASI ET AL.

Raymond Mehler
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed August 14, 2010 appealing from the Office action mailed March 24, 2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1-5, 8, 9, 11-13, 15-17, 20-25, 27, 29, 37, 40-41, 43, 44 and 46-48.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

6,827,963	Aoyama	12-2004
6,589,588	Wester	7-2003

Anon. 2002. Code of Federal Regulations 21 CFR 101.83, p 146-149.

St-Onge, M. 2003. Journal of Nutrition 133:1815.

Swern, D. 1979. Bailey's Industrial Oil and Fat Products, volume 1, 4th edition. John Wiley & Sons, New York. p. 178-180, 192-196, 210-212.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 8-9, 11-13, 15-17, 20-25, 27, 29, 37, 40-41, 43-44 and 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoyama (6,827,963) in view of Wester (6,589,688), CFR and St-Onge taken together as further evidenced by Baileys.

Aoyama discloses fats and oils for reducing lipids in the blood. The patent discloses the preparation of triglycerides from tricaprylin and oleic acid in the case of example 1; sunflower oil and caprylic acid in example 2 and triolein and caprylic in example 3. The synthesized triglycerides were treated to remove free fatty acids to provide triglyceride compositions

shown in tables 1 and 4. The examples all use interesterification to prepare the triglycerides and at column 8, lines 18-23 the use of random or chemical interesterification is suggested. The synthesized triglycerides were used in test diets to show the healthful benefits of reduction of lipids in the blood. The claims appear to differ from Aoyama in the recitation of way the triglycerides are made in claim 1. Aoyama utilizes a combination of a fatty acid and a triglyceride to provide a triglyceride containing medium chain fatty acids. Appellant utilizes two triglycerides in a randomization reaction. The final product in both the claims and Aoyama is a triglyceride containing both medium chain fatty acids and long chain fatty acids.

Aoyama describes his product as containing any of the possible combinations of medium and long chain fatty acids that can form a triglyceride, as shown in the formulas set forth on columns 2 and 3. The suggested triglycerides shown in Aoyama do not appear to favor one triglyceride over the other. Further, it would have been obvious to combine the triglycerides from the examples 1-3 to modify the triglyceride assortment in the diet. The claims also appear to differ from Aoyama in the inclusion of a phytosterol component. Wester is relied upon to show that incorporation of phytosterol esters in foods acts to lower the cholesterol of

the body (column 1, lines 13-37). The concept of using phytosterol in cooking oils is specifically outlined in Wester at column 5, lines 35-37. CFR is relied upon to show the levels of phytosterol ester fortification required to make labeling claims with regard to lowering cholesterol and reducing the risk of coronary heart disease at page 147(G)(1) & (2). Finally St-Onge teaches that oils rich in phytosterols and medium chain triglyceride oil are known in the art to improve plasma lipid profiles in man. With the references of Wester, CFR and St-Onge before him, it would have been obvious to one of ordinary skill in the art to fortify the oil of Aoyama with phytosterol esters to enhance the health benefits of the oil. It is appreciated that the viscosity of the structured lipid is not mentioned but triglycerides are known in the art to have a viscosity within the range of the claims and Baileys in Figure 3.1 on page 180 is relied on for support of this assertion. Also the smoke point is not mentioned but Baileys provides evidence that the smoke point of vegetable oil is around 450F. The smoke point is said to decrease with increasing free fatty acid content and Baileys at pages 211-212 is cited for support of this assertion. Aoyama treats his oils to reduce the free fatty acid content of his triglyceride. One of ordinary skill in the art would expect the smoke point of Aoyama to fall within the

range of the claims. Finally Baileys is relied upon in Table 3.11 at pages 194-195 to show the melting point of oleic acid and C8-C10 separately in triglyceride form. Both triolein and tricaprylin have a melting point of within the range of the claims. One of ordinary skill in the art would expect the interesterified mixture of fats in Aoyama to also have this melting point. It is appreciated that the storage stability and taste of the oil is not mentioned but one of ordinary skill in the art would have expected the triglyceride of Aoyama to have good storage stability and taste because of the saturated fatty acid content of the triglyceride. One would not expect the oil of Aoyama to readily oxidize. To administer one particular amount of oil or the other would have been an obvious way to modify the caloric content of the diet.

The claims indicate that the fat portion of the composition is prepared by a randomization reaction. Appellant defines randomization at page 4, paragraph 7 with cited patents to describe chemical interesterification of fatty acid moieties to create a triglyceride. Aoyama contemplates this mode of interesterification at column 8, lines 19-23.

(10) Response to Argument

Claim 1

Appellant argues that he is performing a randomization reaction and thus cannot provide specific formulas for what triglycerides would form from his reaction. This has been considered but does not overcome the rejection. Aoyama shows the structural formulas possible from the interesterification reaction of medium and long chain fatty acid sources with a source of glycerol. Examiner does not believe that the structural formulas of Aoyama and the claims are different.

Appellant argues Aoyama's only reference to using chemical synthesis is at column 8, lines 20-21 and that Aoyama has not provided an enabling disclosure for using chemical synthesis. This has been considered but is not persuasive. Chemical synthesis for randomization reactions and interesterification is very well known in the art. Appellant admits that chemical randomization is known at page 4, paragraph 7. The specification defines randomization at page 4, paragraph 7 with four cited patents to describe chemical interesterification of fatty acid moieties to create a triglyceride.

Appellant argues that the secondary references to Wester, CFR, St-Onge and Bailey are not concerned with interesterification. Appellant urges that one would need more guidance on how to use the chemical synthesis. But one of ordinary skill in the art would be expected to have access to the previous four patents on randomization that were cited in Appellants' specification.

Appellant argues that Aoyama does not disclose Appellants' liquid structured lipid component. This is disagreed with. Claim 1 is a randomized interesterified product between a medium chain triglyceride and a long chain triglyceride. One of ordinary skill in the art would expect the triglycerides of Table 1 of Aoyama to result from this reaction. Varieties of triglycerides are formed with random placement medium or long chain fatty acids on the glycerol molecule.

Appellant argues that chemical synthesis is not the same thing as random interesterification. Appellant defines interesterification as a randomizing reaction in paragraph 7 of his specification. The fact that Aoyama does not select this method in his examples is not seen to overcome the rejection because Aoyama provides for alternative way to prepare the triglyceride.

THE SECONDARY REFERENCES

Appellant argues that the secondary references do not teach random interesterification. This has been considered. The secondary references are not relied upon to show random interesterification.

CLAIM 15

Appellant argues that the references do not show a clear liquid that remains clear for six months. It is appreciated that Aoyama does not show the clear liquid structured lipid that is clear for six months. Baileys is relied upon in Table 3.11 at pages 194-195 to show the melting point of oleic acid and C8-C10 separately in triglyceride form. This data suggest that these fatty acids are liquid at room temperature. One of ordinary skill in the art would expect the structured lipid to be clear for six months because the structure lipid triglyceride is derived from fatty acids that are liquid.

CLAIM 16

Appellant argues that the composition has sensory qualities that are similar if not better than oil that does not have phytosterol in it. It is appreciated that the taste of the oil of Aoyama is not mentioned but one of ordinary skill in the art would not expect the oil of Aoyama to have a different taste when phytosterol is included. The phytosterol containing oil

has the added health improving values as urged by CFR, Wester and St-Onge.

CLAIM 17

Appellant argues that the composition has sensory qualities that are similar if not better than oil that does not have phytosterol in it. It is appreciated that the taste of the oil of Aoyama is not mentioned but one of ordinary skill in the art would not expect the oil of Aoyama to have a different taste when phytosterol is included. The phytosterol containing oil has the added health improving values as urged by CFR, Wester and St-Onge.

CLAIM 37

Appellant argues that claim 37 is directed to a process and so the randomizing reaction is essential to the claim. Appellant argues that he is performing a randomization reaction and thus cannot provide specific formulas for what triglycerides would form from his reaction. This has been considered but does not overcome the rejection. Aoyama merely shows the structural formulas possible from the triglyceride forming reaction of the combination of the first and second fatty acids. Examiner does not believe that the structural formulas of Aoyama and the claims are different.

Appellant argues Aoyama's only reference to using chemical synthesis is at column 8, lines 20-21 and that Aoyama has not provided an enabling disclosure for using chemical synthesis. This has been considered but is not persuasive. Chemical synthesis for randomization reactions and interesterification is very well known in the art. Appellant admits that chemical randomization is known at page 4, paragraph 7. The specification defines randomization at page 4, paragraph 7 with four cited patents to describe chemical interesterification of fatty acid moieties to create a triglyceride.

Appellant argues that the secondary references to Wester, CFR, St-Onge and Bailey are not concerned with interesterification. Appellant urges that one would need more guidance on how to use the chemical synthesis. But one of ordinary skill in the art would be expected to have access to the four patents on randomization that were cited in Appellants' specification.

Appellant argues that Aoyama does not disclose Appellants' liquid structured lipid component. This is disagreed with. Claim 37 is a randomized interesterified product between a medium chain fatty acid source and a long chain fatty acid source. One of ordinary skill in the art would expect the triglycerides of Table 1 of Aoyama to result from this

reaction. Varieties are formed with random placement medium or long chain fatty acids on the glycerol molecule.

Appellant argues that chemical synthesis is not the same thing as random interesterification. Appellant defines interesterification as a randomizing reaction in paragraph 7 of his specification. The fact that Aoyama does not select this method to make his product is not seen to overcome the rejection because Aoyama provides for alternative way to prepare the triglyceride.

CLAIM 40 and Dependent claims 41, 43, 44 and 46

Appellant argues that claim 40 requires randomized interesterification that is not disclosed by Aoyama. This has been considered but is not persuasive. Aoyama and St-Onge both disclose that medium chain triglycerides are useful in improving health and nutrition. The LDL cholesterol of people consuming medium chain triglycerides was reduced in both Aoyama and St-Onge. One of ordinary skill in the art would expect the LDL cholesterol of people consuming Appellants' fat to also be reduced because it contains medium chain fatty acids.

CLAIM 47

Appellant argues that the references do not show a clear liquid that remains clear for six months. It is appreciated that Aoyama does not show the clear liquid structured lipid that is clear for six months. Baileys is relied upon in Table 3.11 at pages 194-195 to show the melting point of oleic acid and C8-C10 separately in triglyceride form. This data suggest that these fatty acids are liquid at room temperature. One of ordinary skill in the art would expect the structured lipid to be clear for six months because the structure lipid triglyceride is derived from fatty acids that are liquid.

CLAIM 48

Appellant argues that the composition has sensory qualities that are similar if not better than oil that does not have phytosterol in it. It is appreciated that the taste of the oil of Aoyama is not mentioned but one of ordinary skill in the art would not expect the oil of Aoyama to have a different taste when phytosterol is included. The phytosterol containing oil has the added health improving values as urged by CFR, Wester and St-Onge.

Appellant urges that his product is even better than the medium chain triglyceride used in St-Onge. This has been considered but is not

persuasive that the claims are unobvious over the references. The claims merely call for an improvement in LDL cholesterol reduction. The subjects tested in St-Onge were different from the subjects tested in Rudkowska in that the Rudkowska subjects were hyperlipidemic at the start of the testing. One would expect more improvement in the hyperlipidemic subjects because of the bigger change in diet that occurred as a result of the test. The Rudkowska test was not designed to compare Aoyama in view of Wester, CFR, St-Onge and Baileys with Appellants' randomly interesterified structured lipid composition.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Carolyn Paden/

Conferees:

/Keith D. Hendricks/
Supervisory Patent Examiner, Art Unit 1781

/Gregory L Mills/
Supervisory Patent Examiner, Art Unit 1700